

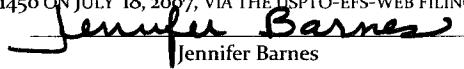
PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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<b>Title:</b> CARDIAC SUPPORT DEVICE WITH DIFFERENTIAL EXPANSION	<b>Docket No.</b> 59013-331629 <b>Customer No.:</b> 25764

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**APPEAL BRIEF**

The Applicant filed a Notice of Appeal on December 8, 2006 from the Final Office Action dated September 8, 2006. The arguments in this brief are responsive to the status and disposition of the pending claims as represented by the Final Office Action mailed on September 8, 2006 and Notice of Panel Decision from Pre-Appeal Brief Review mailed on January 18, 2007. This Appeal is proper because the present application includes claims that have either been twice rejected or finally rejected. The Applicant's Brief in support of this Appeal includes each section required by 37 C.F.R. §41.37.

Enclosed with this brief are the following documents:

1. Request for fifth-month extension of time.
2. Credit card charge authorization for the fees required for the filing of this brief and the extension of time.

The Commissioner is authorized to charge any additional fees or credit any overpayment to Deposit Account No. 06-0029 and requested to notify us of the same.

**1. REAL PARTY IN INTEREST**

The real party in interest is Acorn Cardiovascular, Inc. the assignee of record.

**2. RELATED APPEALS AND INTERFERENCES**

There are no known related appeals or interferences.

**3. STATUS OF CLAIMS**

Claims 18, 19, 22, 23, 25, 26, 28, 34 and 35 stand rejected and are the subject of this appeal. Claims 1-17, 20-21, 24, 27, and 29-33 have been canceled. Claims 36 and 37 are allowed.

**4. STATUS OF AMENDMENTS**

No claim amendments have been submitted by the Applicant subsequent to the Final Office Action mailed on September 8, 2006 (“Office Action”). Thus, there are no filed but un-entered claim amendments.

**5. SUMMARY OF CLAIMED SUBJECT MATTER**

The claimed subject matter is directed to a device for treating a disease of the heart, and include several structural features relating to the configuration of the claimed device for placement on a heart and for constraining circumferential expansion of the heart. The device exhibits differential expansion characteristics depending on the direction of application of force on the jacket by the heart. As disclosed in the specification, for example, at page 14, lines 8-29, the claimed device provides substantial advantages, including constraining circumferential expansion of the heart while not impeding other motion of the heart.

In particular, independent claim 18 recites a device for treating a disease of a heart. The device comprises a jacket (10, 10') dimensioned to be placed on the heart with the jacket surrounding at least a lower portion of the heart. FIGS. 3, 3A, 4, 4A; page 9, l. 22 – page 10,

line 8. The jacket is sized and shaped to snugly conform to an external geometry of the heart to constrain circumferential expansion of the heart during diastole and permit substantially unimpeded contraction of the heart during systole. Page 10, l. 9 – page 12, l. 10. The jacket has an open base end (12, 12') sized to be placed over the heart and to surround at least the valvular annulus of the heart. FIGS. 3, 3A, 4, 4A; page 11, ll. 3-6. Additionally, the jacket has a length sized to extend from the base end to an apex end (14, 14') sized to surround the heart near the apex of the heart. *Id.*, ll. 6-8. The direction between the base end and the apex end of the jacket defines a longitudinal dimension. The jacket is constructed from a biocompatible material selected to exhibit an amount of expansion in response to a force applied to the material by the heart in a first direction greater than the amount of expansion in response to the force applied to the material by the heart in a second direction, with the material oriented on the jacket with the first direction extending in a direction substantially aligned with the longitudinal dimension and the second direction aligned substantially transverse to the first direction. Page 12, ll. 22-30 As such, the jacket is more readily expandable in the longitudinal dimension than in a direction transverse to the longitudinal dimension.

The appealed dependent claims 19, 22, 23, 25, 26, 28, 34 and 35 all depend, either directly or indirectly, from independent claim 18. For purposes of this Appeal only, independent claim 18 and dependent claims 19, 22, 23, 25, 26, 28, 34 and 35 stand or fall together as a group. Accordingly, the arguments presented below address only independent claim 18.

## **6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

**Ground of Rejection 1:** Whether claims 18, 19, 22, 23, 28 and 35 are unpatentable under 35 U.S.C. § 102(e) over U.S. Patent No. 5,839,842 to Wanat, et al. (the “Wanat patent”)

**Ground of Rejection 2:** Whether claims 18, 19, 22, 23, 26, 28, 34 and 35 are unpatentable under 35 U.S.C. § 102(b) over U.S. Patent No. 1,682,119 to Field (the “Field patent”).

**Ground of Rejection 3:** Whether claims 18, 19, 22, 23, 28 and 34 are unpatentable under 35 U.S.C. § 102(b) over U.S. Patent No. 3,551,543 to Mercer, et al. (the “Mercer patent”).

**Ground of Rejection 4:** Whether claims 18, 19, 22, 23, 25, 28, 34 and 35 are unpatentable under 35 U.S.C. § 102(b) over U.S. Patent No. 2,376,452 to Mehler (the “Mehler patent”).

## ARGUMENT

### The Pending Claims Are Not Anticipated by the Cited References

The references cited by the Examiner do not anticipate any of the pending claims. The Applicant respectfully believes that the Examiner has not given due consideration to the structural features of the pending claims. These structural features distinguish the pending claims over the cited references, which have nothing to do with devices for treating diseases of the heart, and as discussed below, fail to disclose or fairly suggest devices structurally configured for treating diseases of the heart.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *See* Manual of Patent Examining Procedure, § 2131. The identical invention must be shown in as complete detail as is contained in the claim. *See id.* In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *See id.* at § 2112 (citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)). The extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *See In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949 (Fed. Cir. 1999)(reversing Board’s finding of anticipation based on inherency).

The rejected claims recite a device for treating a disease of the heart, and include several structural features relating to the configuration of the claimed device for placement on a heart and for constraining circumferential expansion of the heart. In particular,

independent claim 18, from which all other rejected claims depend, recites that the device comprises a jacket dimensioned to be placed on the heart, surrounding at least a lower portion of the heart, and sized and shaped to snugly conform to an external geometry of the heart. Claim 18 further recites that the jacket is constructed from a biocompatible material selected to exhibit an amount of expansion in response to a force applied to the material by a heart in a first direction greater than an amount of expansion in response to the force applied to the material by a heart in a second direction. Thus, the device exhibits differential expansion characteristics depending on the direction of application of force on the jacket by the heart.

In contrast, however, the prior art patents relied upon in the Office Action have nothing to do with devices for treating a disease of the heart. Rather, the cited prior art patents disclose, in turn: (1) a “cleansing kit” including an open cell mesh bag enclosing a sponge and a toilet bar (the Wanat Patent); (2) a cleaning device including a soap contained in an “envelope or container” made from a soft metal mesh (including aluminum, copper, and “German Silver,” a copper alloy) having “scraping edges” for scraping the surface to be cleaned (the Field patent); (3) a method for extruding a plastic net in a sheet or tubular form (the Mercer patent); and (4) “tubular netting” primarily for the lowering of dynamite or other explosives in drill holes (the Mehler patent). None of the cited references disclose a jacket sized and shaped to snugly conform to an external geometry of the heart, much less do any disclose such a device having differential expansion characteristics depending on the direction of force applied to the device by the heart. Accordingly, the cited references cannot anticipate the claims currently under rejection.

**Ground of Rejection 1:**

***The Wanat Patent does not Anticipate Claims 18, 19, 22, 23, 28 and 35 Under 35 U.S.C. § 102(e).***

The Wanat patent discloses a “cleansing kit” including an “open cell mesh bag” enclosing a sponge and a toilet bar. *See Fig.; see also Col. 2, ll. 7-21.* The Examiner cites to the mesh bag (2) as disclosing the jacket of claim 18, and asserts that “if one selects a heart of the appropriate size any size net would meet the relative limitations set forth in the claims.” Office Action at 3. The Examiner further asserts that the device of the Wanat

patent is “inherently capable of performing the other functions set forth in the functional language of the claim.” *Id.* at 2-3. A fair reading of the Wanat patent, however, confirms that it discloses almost none of the features of the claimed invention as set forth in independent claim 18. In fact, the most that can be said for Wanat is that it discloses a device that may be formed of polyethylene, which in some cases could arguably constitute a biocompatible material.

First, the Wanat patent does not teach or fairly suggest that its “netted mesh” pouch is shaped to snugly conform to an external geometry of a heart to constrain circumferential expansion of the heart during diastole and permit substantially unimpeded contraction of the heart during systole. To the contrary, the shapes of the items enclosed by the “netted mesh” pouch of Wanat (e.g., a sponge in the shape of a hand and a “toilet bar”) are entirely different than the human heart. Compare, e.g., the figure of Wanat with FIGS. 1-1B and 2-2B of the pending application. Moreover, nothing in the Wanat patent suggests that the mesh pouch is shaped to snugly conform to its contents, regardless of their shapes, or to constrain expansion of its contents. The mesh pouch of the Wanat patent merely provides a receptacle to contain the other components of the disclosed “cleansing kit” – i.e., the sponge 14, toilet bar 16, and an instruction sheet 18.

The Examiner nevertheless asserts that “if one selects a heart of the appropriate size any size net would meet the relative limitations set forth in the claims,” and that “tubular mesh bags assume the shape of whatever is placed inside of them therefore meets the limitation of being shaped to snugly conform to an external geometry of the heart.” Office Action at 3. The Examiner has provided no support, whether in the Wanat patent or anywhere else, for this broad contention. Even the Figure of the Wanat patent itself refutes this contention, as it illustrates gaps and slack between the mesh pouch 2 and the sponge 14. Thus, the mesh pouch 2 of the Wanat patent does not necessarily snugly conform to its contents. Furthermore, the claimed invention does not merely include a generic tubular jacket. Rather, it requires a jacket having a specific size and shape so as to snugly conform to the heart on which it is placed. This is plainly not disclosed in the Wanat patent.

Moreover, the claimed invention not only requires the jacket to be sized and shaped to snugly conform to the external geometry of the heart, but also to constrain circumferential

expansion of the heart during diastole and permit substantially unimpeded contraction of the heart during systole. The Examiner has apparently completely ignored these claimed features. This is clearly improper. The Examiner has provided no support in the cited references for the position that any “mesh bag[],” regardless of its specific size and shape, will necessarily both snugly conform to the external geometry of the heart, but also to constrain circumferential expansion of the heart during diastole and permit substantially unimpeded contraction of the heart during systole. Furthermore, as can be seen in Figs. 1 and 1A of the pending application, the heart has a relatively narrow apex region, increases in diameter toward the base, then narrows again at the A-V groove. It is thus not uniform in diameter from the apex to the A-V groove. Additionally, as shown in Figs. 2 and 2A, this non-uniformity can be even more pronounced with a heart deformed by congestive heart disease. Thus, in the claimed invention, the jacket is specifically sized and shaped to snugly conform to the heart to constrain circumferential expansion of the heart during diastole and permit substantially unimpeded contraction of the heart during systole. Nothing in the Wanat patent, or any of the other cited references, discloses or suggests a structure that can satisfy this requirement.

Additionally, the Examiner’s reliance on the disclosure at Paragraph [0058] of the pending application as support for the outstanding rejection is misplaced. *See* Office Action at 3. Simply because one disclosed embodiment of the present invention entails adjusting the volume and shape of the jacket after placement on the heart is irrelevant. The jacket of the claimed invention must be sized and shaped to snugly conform to the external geometry of the heart to constrain circumferential expansion of the heart during diastole and permit substantially unimpeded contraction of the heart during systole. Whether this structure is formed before or after placement of the jacket on the patient’s heart is irrelevant. The fact of the matter is that the Wanat patent fails to disclose this and the other structural features of the claimed invention as explained above.

Second, the Wanat patent fails to mention any expansion characteristics of the disclosed “netted mesh” pouch, nor does it suggest that the contents of the “cleansing kit” expand or contract in any way. Thus, the Wanat patent cannot disclose the differential expansion features of the claimed invention. That is, the Wanat patent fails to disclose or

suggest a biocompatible material that exhibits an amount of expansion in response to a force applied in one direction by a heart greater than an amount of expansion in response to the force applied by the heart in a second direction. The Examiner disposes of these claimed requirements by asserting that they are merely directed to an intended use of the device. Office Action at 8-9. This is clearly erroneous when considering the claimed invention as a whole. Rather, the requirements regarding the size and shape of the jacket and its differential expansion characteristics constitute claimed structural and functional features that clearly distinguish the claimed invention from generic mesh structures such as that disclosed in the Wanat patent and the other cited references.

Moreover, in the claimed invention, the jacket is more readily expandable in the direction corresponding to the dimension between the base end and the apex end of the heart than in the direction transverse to that dimension. None of these claimed features are disclosed, either explicitly or implicitly, in the Wanat patent, which has nothing to do with a device for placement on or treating a disease of the heart. Indeed, the Examiner provides no support for the assertion that the “diamond pattern” of Wanat pouch “allows for differential expansion of the jacket.” The Wanat patent makes no mention of the expansion characteristics, if any, of the disclosed pouch 2, much less any differential expansion characteristics. This is simply not discussed in the Wanat patent.

Finally, the Examiner’s reliance on inherency principles to supply the numerous claim elements missing from the Wanat patent should also be rejected. The Examiner asserts that the device of the Wanat patent is “inherently capable of performing the other functions set forth in the functional language of the claim.” Office Action at 3. But the Examiner has the burden of providing a basis in fact and/or technical reasoning to support the contention that the allegedly inherent characteristic necessarily flows from the teachings of the Wanat patent. The Examiner’s unsupported conclusion that the “diamond pattern” of the pouch in the Wanat patent is inherently capable of satisfying the requirements of the claimed invention is precisely the type of reasoning that the United States Court of Appeals for the Federal Circuit has squarely rejected. *See, e.g., In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949, (Fed. Cir. 1999). The Examiner’s position regarding inherency cannot be sustained.

Thus, for at least these reasons, the Wanat patent does not anticipate claim 18. The rejection of claims 18, 19, 22, 23, 28, and 35 based on the Wanat patent is therefore improper.

In view of the foregoing, the Applicant respectfully requests reconsideration and withdrawal of the rejection claims 18, 19, 22, 23, 28, and 35 under 35 U.S.C. § 102(e) based on the Wanat patent.

**Ground of Rejection 2:**

***The Field Patent does not Anticipate Claims 18, 19, 22, 23, 26, 28, 34 and 35 under 35 U.S.C. § 102(b).***

The Field patent discloses and claims a cleaning device including a soap contained in an “envelope or container” made from a metallic mesh. *See* Figs. 1-2; *see also* page 1, ll. 35-57. The disclosed metallic mesh envelope provides “scraping edges” for “scraping the surface to be cleaned.” *See* page 2, ll. 4-15. The Examiner cites the metallic envelope 2 as disclosing the claimed jacket. Like the Wanat patent, the Field patent clearly has nothing to do with a jacket for placement on and treating a disease of the heart, and cannot anticipate the rejected claims.

First, the Field patent does not teach or fairly suggest that its “metallic envelope” is shaped to snugly conform to an external geometry of a heart to constrain circumferential expansion of the heart during diastole and permit substantially unimpeded contraction of the heart during systole. To the contrary, the shape of the contents of the metallic mesh envelope is entirely different than the shape of the heart. Compare Fig. 1 of the Field patent with FIGS. 1-1B and 2-2B of the pending application. Thus, the Field patent fails to disclose or suggest a jacket sized and shaped to snugly conform to an external geometry of the heart, as recited in claim 18, regardless of the size of the heart.

The Examiner nevertheless asserts that “if one selects a heart of the appropriate size any size net would meet the relative limitations set forth in the claims” that “the shape of the envelope -2- will be determined by what is placed in the envelope,” and that “the material pattern allows for the shape to be adjusted.” Office Action at 4. But the Field patent specification is silent on the specific size and shape of the disclosed “cleaning device”

beyond that shown in its figures, and the Examiner has provided no support for the contention that the metallic envelope -2- will inherently “snugly conform” to a heart even if it could be placed thereon. Moreover, as with the Wanat patent, the Examiner has ignored the requirement of the claimed invention that the jacket be sized and shaped to not only snugly conform to the external geometry of the heart, but also to constrain circumferential expansion of the heart during diastole and permit substantially unimpeded contraction of the heart during systole. For at least the reasons explained above with respect to the Wanat patent, this is clearly improper.

Furthermore, as with the other cited references, Paragraph [0058] of the present application provides no support for the outstanding rejection. *Id.* at 4-5. The claimed invention requires that the jacket be sized and shaped to snugly conform to the external geometry of the heart to constrain circumferential expansion of the heart during diastole and permit substantially unimpeded contraction of the heart during systole. This requirement is not diminished merely because in one embodiment the structure is completed after placement of the jacket on the patient’s heart. The Field patent plainly does not disclose this structure, nor has the Examiner explained how or why it is necessarily present or necessarily flows from the teachings of the Field patent.

Second, as with the Wanat patent, the Field patent fails to disclose or suggest a biocompatible material selected to exhibit an amount of expansion in response to a force applied to the material by a heart in a first direction greater than an amount of expansion in response to the force applied to the material by a heart in a second direction, as claimed in claim 18. Thus, the Field patent cannot disclose the differential expansion features of the claimed invention as described above with respect to the Wanat patent.

Nevertheless, the Examiner asserts that the “material pattern shown in figure 3 and arranged as shown in figure 1 provides for a jacket having the particular expansion properties as claimed in the functional language set forth in the claims,” and that the “interconnected rows of hinges provide for expansion and contraction in the circumferential direction without affecting the length of the envelope.” Office Action at 4. But the Field patent is silent as to the expansion characteristics of the disclosed metallic mesh envelope. At most, the Field patent refers to “springiness” of the disclosed metal fabric and “elastic stiffness” of the

ribbon loops making. *See* page 1, ll. 109-110 through page 2, ll. 1-11. But as disclosed, these features operate to “permit the ribbons to assume a characteristic position more or less edgewise to the surface.” *Id.* Accordingly, this “present[s] the scraping edges of the ribbon edgewise to the surface of the fabric and consequently in the best possible position for scraping the surface to be cleaned,” and also to provide openings for the flow of water through the fabric. *Id.*, ll. 10-17. The disclosure has nothing to do with differential expansion of the fabric in response to forces applied by the contents of the envelope. Indeed, there is no teaching or suggestion in the Field patent that the contents of the metallic envelope – soap chips – expand during use, and so the expansion characteristics of the disclosed envelope would appear to be irrelevant to the teachings of the Field patent. Moreover, the Applicant is unable to find any reference in the Field patent to the disclosed envelope as including “hinges.” Finally, the Field patent plainly does not teach or fairly suggest such differential expansion characteristics in response to a force applied by a heart in different directions. Nor does the Field patent teach or fairly suggest the specific orientation of the claimed jacket such that the more compliant dimension of the jacket corresponds to the direction between the base and apex of the heart when placed thereon, or the associated advantages.

To the extent that the Examiner is asserting that the differential expansion characteristics of the claimed invention are inherently present in the metallic envelope of the Field patent, the Examiner has altogether failed to satisfy his burden of a basis in fact and/or technical reasoning to support the contention that these characteristics are necessarily present in or necessarily flow from the teachings of the Field patent. As with the Wanat patent, the Examiner’s reliance on inherency principles to support the anticipation rejections based on the Field patent cannot be sustained.

Third, the Field patent discloses the metallic mesh envelope 2 as being made from “relatively soft metals or alloys such as copper, aluminum, or German silver,” *see* page 1, ll. 52-55, the latter being generally understood to be a copper alloy. Thus, the Examiner erred in concluding that “German silver” is a biocompatible material as claimed. Finally, the metallic envelope of the Field patent includes “scraping edges” which render the metallic mesh envelope wholly unsuitable as a jacket sized and shaped to snugly conform to an

external geometry of a heart. Both of these teachings of the Field patent further emphasize the differences between it and the claimed invention.

Thus, for at least these reasons, the Field patent does not anticipate claim 18. The rejection of claims 18, 19, 22, 23, 26, 28, 34, and 35 based on the Field patent is therefore improper.

In view of the foregoing, the Applicant respectfully requests reconsideration and withdrawal of the rejection claims 18, 19, 22, 23, 26, 28, 34, and 35 under 35 U.S.C. § 102(b) based on the Field patent.

**Ground of Rejection 3:**

***The Mercer Patent does not Anticipate Claims 18, 19, 22, 23, 28 and 34 under 35 U.S.C. § 102(b).***

The Mercer patent discloses, in relevant part, a method for extruding a plastic net in a sheet or tubular form. Col. 4, ll. 48-71. No other shapes for the disclosed net are taught. The Mercer patent does not even disclose any particular purposes or uses for the disclosed net. At most, the Mercer patent discloses a net material that is “dimensionally stable” in one direction, but which has “extensibility (i.e., is not dimensionally stable)” in a direction transverse to that direction. Col. 3, ll. 27-42. The Mercer patent falls far short, however, of disclosing each and every element of the claimed invention. Indeed, the Mercer patent also states that nets in a diamond mesh form will have extensibility in two directions transverse to each other and will thus “behave as a conventional diamond mesh net.” *See* Col. 3, ll. 48-51. If anything, this disclosure tends to refute the Examiner’s position, stated in connection with the Wanat and Mehler references, that a material with a “diamond pattern” will be “inherently capable” of satisfying the differential expansion characteristics of the claimed invention. *See* Office Action at 2-3, 5-6.

The Mercer patent clearly does not disclose or suggest a sheet or tubular net does not disclose or fairly suggest that is sized and shaped to snugly conform to an external geometry of a heart to constrain circumferential expansion of the heart during diastole and permit substantially unimpeded contraction of the heart during systole. Like the other cited references, the Mercer patent has nothing to do with devices for treating a disease of the

heart. The Applicant can find no support for the Examiner's assertions that "the shape of the tubular net will be determined by what is placed in the envelope." Office Action at 5-6. To the contrary, as explained above in with respect to the Wanat patent, a generic tubular net will not necessarily satisfy the requirements of snugly conforming to the external geometry of the heart to constrain circumferential expansion of the heart during diastole and permit substantially unimpeded contraction of the heart during systole. Furthermore, even if the disclosed material pattern of the Mercer patent "allows for the shape to be adjusted," Office Action at 5-6, this is irrelevant.

Here again, the Examiner's reliance on the disclosure in Paragraph [0058] of the present application is misplaced. *Id.* at 6. As explained above, the claimed invention includes the requirement that the jacket be sized and shaped to snugly conform to the external geometry of the heart to constrain circumferential expansion of the heart during diastole and permit substantially unimpeded contraction of the heart during systole. This requirement is not diminished merely because in one embodiment the structure is completed after placement of the jacket on the patient's heart. The Mercer patent plainly does not disclose this structure, nor has the Examiner explained how or why it is necessarily present or necessarily flows from the teachings of the Mercer patent.

With respect to the differential expansion characteristics of the claimed invention, the Examiner asserts that the net of the Mercer patent is "specifically designed to have differential expansion properties wherein the jacket is more readily expandable in the longitudinal direction than in a direction transverse to the longitudinal direction." Office Action at 5. But the Mercer patent does not disclose any actual structure or form for the net material beyond references to a "sheet or tubular net." It does not teach or disclose a "longitudinal direction," much less the specific orientation of the claimed jacket such that the more compliant dimension of the jacket corresponds to the direction between the base and apex of the heart, or the associated advantages. Furthermore, for the same reasons explained above with respect to the Wanat patent, the Examiner's contention that the claim requirement that the biocompatible material exhibits an amount of expansion in response to a force applied in one direction by a heart greater than an amount of expansion in response to the

force applied by the heart in a second direction is merely an intended use, *see* Office Action at 10, is clearly erroneous when considering the claimed invention as a whole.

Thus, for at least these reasons, the Mercer patent does not anticipate claim 18. The rejection of claims 18, 19, 22, 23, 28, and 34 based on the Mercer patent is therefore improper.

In view of the foregoing, the Applicant respectfully requests reconsideration and withdrawal of the rejection claims 18, 19, 22, 23, 28, and 34 under 35 U.S.C. § 102(b) based on the Mercer patent.

**Ground of Rejection 4:**

***The Mehler Patent does not Anticipate Claims 18, 19, 22, 23, 25, 28, 34 and 35 under 35 U.S.C. § 102(b).***

The Mehler patent discloses “tubular netting,” and is “concerned primarily with the lowering of dynamite or other explosives in drill holes.” Col. 1, ll. 1-6. As such, the net of the Mehler patent eliminates the knots joining individual cords in conventional nets of the time. As disclosed, such knots created impediments to inserting the dynamite sticks into the net, and also caused the net to catch in restricted portions of the bore, thereby impairing advancement or even removal of the charges from the drill holes. *See id.*, ll. 7-20, ll. 33-54. The only disclosed shape for the netting is tubular. Like the other cited references, the Mehler patent has nothing to do with a device for placement on and treating a disease of the heart.

The Mehler patent fails to teach or suggest a tubular netting that is shaped to snugly conform to the external geometry of a heart to constrain circumferential expansion of the heart during diastole and permit substantially unimpeded contraction of the heart during systole. To the contrary, the Mehler patent explicitly teaches that an object of the invention disclosed the provision of a tubular netting “which is substantially uniform in diameter.” Col. 2, ll. 41-44. As can perhaps best be seen in FIGS. 1-1B and 2-2b of the pending application, a tubular netting, particularly one that is substantially uniform in diameter as disclosed in the Mehler patent, will not necessarily satisfy the requirements of snugly conforming to the external geometry of the heart to constrain circumferential expansion of

the heart during diastole and permit substantially unimpeded contraction of the heart during systole.

Furthermore, as with the other cited references, the Examiner's reliance on the disclosure in Paragraph [0058] of the present application is misplaced. *Id.* at 7-8. The claimed invention requires that the jacket be sized and shaped to snugly conform to the external geometry of the heart to constrain circumferential expansion of the heart during diastole and permit substantially unimpeded contraction of the heart during systole. This requirement is not diminished merely because in one embodiment the structure is completed after placement of the jacket on the patient's heart. The Mehler patent plainly does not disclose this structure, nor has the Examiner explained how or why it is necessarily present or necessarily flows from the teachings of the Mehler patent. As with the other cited references, Paragraph [0058] of the present application fails to support the Examiner's rejection based on the Mehler patent.

As to the claimed differential expansion characteristics, the Mehler patent is silent as to the expansion characteristics of the disclosed net. The Examiner applies substantially the same reasoning regarding the Mehler patent as discussed above with respect to the Wanat patent. In short, the Examiner points to the "diamond pattern" of the disclosed netting and asserts that this pattern "determines expansion and contraction in the circumferential and longitudinal direction." Office Action at 6-7. Again, however, the Mehler patent is silent as to any expansion characteristics of its disclosed netting. Thus, as with the Wanat patent discussed above, the Mehler patent does not disclose the claimed differential expansion features. And as with all of the other cited references, to the extent that the Examiner is asserting that the differential expansion characteristics of the claimed invention are inherently present in the netting of the Mehler patent, the Examiner has altogether failed to satisfy his burden of a basis in fact and/or technical reasoning to support the contention that these characteristics are necessarily present in or necessarily flow from the teachings of the Mehler patent.

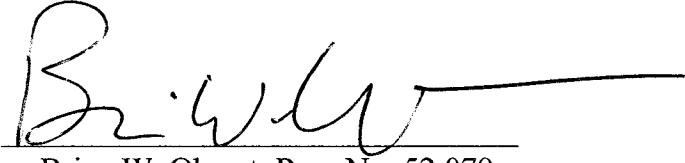
Thus, for at least these reasons, the Mehler patent does not anticipate claim 18. The rejection of claims 18, 19, 22, 23, 25, 28, 34 and 35 based on the Mehler patent is therefore improper.

In view of the foregoing, the Applicant respectfully requests reconsideration and withdrawal of the rejection claims 18, 19, 22, 23, 25, 28, 34 and 35 under 35 U.S.C. § 102(b) based on the Mehler patent.

### CONCLUSION

The claims under appeal recite a device for treating a disease of the heart, and include several structural features relating to the configuration of the claimed device for placement on a heart and for constraining circumferential expansion of the heart. The device exhibits differential expansion characteristics depending on the direction of application of force on the jacket by the heart. The claimed device provides substantial advantages, including constraining circumferential expansion of the heart while not impeding other motion of the heart. For at least the reasons set forth above, the cited references fail to disclose, teach or suggest this claimed invention. Accordingly, pending claims 18, 19, 22, 23, 25, 26, 28, 34 and 35 are patentable over the prior art of record and are in condition for allowance. The Applicant respectfully requests that the Board reverse the outstanding rejections of the foregoing claims and instruct the Examiner to issue a Notice of Allowance of all pending claims.

Respectfully Submitted,

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Dated: July 18, 2007

## CLAIMS APPENDIX

1-17. (Canceled)

18. (Previously presented) A device for treating a disease of a heart, the device comprising:

a jacket dimensioned to be placed on said heart with said jacket surrounding at least a lower portion of said heart and sized and shaped to snugly conform to an external geometry of said heart to constrain circumferential expansion of said heart during diastole and permit substantially unimpeded contraction of said heart during systole,

said jacket having an open base end sized to be placed over said heart and to surround at least a valvular annulus of said heart and said jacket having a length sized to extend from said base end to an apex end sized to surround said heart near an apex of said heart, a direction between said base end and said apex end defining a longitudinal dimension;

wherein said jacket is constructed from a biocompatible material selected to exhibit an amount of expansion in response to a force applied to said material by a heart in a first direction greater than an amount of expansion in response to said force applied to said material by a heart in a second direction; and

said material oriented on said jacket with said first direction extending in a direction substantially aligned with said longitudinal dimension and said second direction aligned substantially transverse to said first direction;

whereby said jacket is more readily expandable in said longitudinal dimension than in a direction transverse to said longitudinal dimension.

19. (Previously presented) The device of claim 18, wherein said material is formed from a plurality of interconnected elongated members with opposing surfaces of said members defining a plurality of open cells.

20-21. (Canceled)

22. (Previously presented) The device according to claim 18, wherein said jacket is configured to constrain at least a lower portion of the heart.

23. (Previously presented) The device according to claim 18, wherein said jacket is dimensioned so as to circumferentially extend completely around said heart.

24. (Canceled)

25. (Previously presented) The device according to claim 19, wherein said elongated members are formed of a plurality of fibers.

26. (Previously presented) The device according to claim 19, wherein said elongated members are formed of metal.

27. (Canceled)

28. (Previously presented) The device according to claim 18 wherein said jacket is adapted to constrain said heart from expanding beyond a maximum volume.

29-33. (Canceled)

34. (Previously presented) The device according to claim 18, wherein said jacket has an open apex end.

35. (Previously presented) The device according to claim 18, wherein said jacket has a closed apex end.

36. (Previously presented) A device for treating a disease of a heart, the device comprising:

a jacket dimensioned to be placed on said heart with said jacket surrounding at least a lower portion of said heart and sized to snugly conform to an external geometry of said heart to constrain circumferential expansion of said heart during diastole and permit substantially unimpeded contraction of said heart during systole,

said jacket having an open base end sized to be placed over said heart and to surround at least a valvular annulus of said heart and said jacket having a

length sized to extend from said base end to an apex end sized to surround said heart near an apex of said heart, a direction between said base end and said apex end defining a longitudinal dimension;

wherein said jacket is constructed from a biocompatible material selected to exhibit an amount of expansion in response to a force applied to said material in a first direction greater than an amount of expansion in response to said force applied to said material in a second direction; and

wherein said material is formed from a plurality of interconnected elongated members with opposing surfaces of said members defining a plurality of open cells, wherein said elongated members are coated;

said material oriented on said jacket with said first direction extending in a direction substantially aligned with said longitudinal dimension and said second direction aligned substantially transverse to said first direction;

whereby said jacket is more readily expandable in said longitudinal dimension than in a direction transverse to said longitudinal dimension.

37. (Previously presented) A device for treating a disease of a heart, the device comprising:

a jacket dimensioned to be placed on said heart with said jacket surrounding at least a lower portion of said heart and sized to snugly conform to an external geometry of said heart to constrain circumferential expansion of said heart during diastole and permit substantially unimpeded contraction of said heart during systole,

said jacket having an open base end sized to be placed over said heart and to surround at least a valvular annulus of said heart and said jacket having a length sized to extend from said base end to an apex end sized to surround said heart near an apex of said heart, a direction between said base end and said apex end defining a longitudinal dimension;

    wherein said jacket is constructed from a biocompatible material selected to exhibit an amount of expansion in response to a force applied to said material in a first direction greater than an amount of expansion in response to said force applied to said material in a second direction; and

    wherein said material is formed from a plurality of interconnected elongated members with opposing surfaces of said members defining a plurality of open cells, wherein said elongated members are formed of stainless steel;

    said material oriented on said jacket with said first direction extending in a direction substantially aligned with said longitudinal dimension and said second direction aligned substantially transverse to said first direction;

    whereby said jacket is more readily expandable in said longitudinal dimension than in a direction transverse to said longitudinal dimension.

**EVIDENCE APPENDIX**

None.

**RELATED PROCEEDINGS APPENDIX**

None.